

REMARKS

Applicants have amended the claims to more clearly define the claimed invention. In particular, claim 1 has been amended to clarify that the method involves a single step of contacting native endogenous cells (either neural stem cells or neural precursor cells) with a composition that includes granulocyte-macrophage colony stimulating factor (GM-CSF) as the sole active agent. Support for the amendment is found throughout the specification, including for example, in Example 7. Claim 2 has been amended to limit the claim to inducing the proliferation of neural cells *in vitro* by contacting the cells with GM-CSF in media. Support is found in the original claim and on page 11, lines 4-10 of the specification. Claims 3 and 4 have been amended to place the claim in independent form and to specify that the harvested neural cells are proliferated in cell culture by contact with GM-CSF. Support for the amendment is found throughout the specification, including on page 11 lines 16-33. Claim 8 is amended to incorporate the limitation of original claim 9, and claim 9 has been canceled. The remaining claims have been amended to clarify the claim language and focus on the embodiment involving the use of GM-CSF.

Claims 15 and 18 have been canceled as being directed to non-elected subject matter. Claims 1-4, 8, 10 and 16 remain pending in the application.

Claims 1-14, 16 and 17 stand rejected under 35 USC 112, second paragraph for indefiniteness for failure to clearly designate the cell that the phrase "supernatant of the cell" is referencing. The phrase has been removed from all currently pending claims, thus rendering the rejection moot. Accordingly, applicants respectfully request the withdrawal of the rejection under that statutory section.

Claims 8, 12, 14 and 17 stand rejected as being anticipated by Hauben et al. Claim 8 has been amended to specify the kit components are GM-CSF and a culture medium. Hauben et al fails to teach such a combination of elements. Therefore, Hauben et al fail to anticipate the claimed invention of claim 8. Claims 12, 14 and 17 have been canceled, thus rendering the rejection, as to those claims, moot. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 USC 102 based on Hauben et al.

Claims 1, 6-8, 11, 12, 14 and 17 stand rejected under 35 USC 102 as being anticipated by WO/1997/009885. Claims 6, 7, 11, 12, 14 and 17 have been canceled thus rendering the rejection, as to those claims, moot. Claims 1 and 8 have been amended to specify that GM-CSF is the active agent that is used to stimulate the proliferation of neural cells. WO/1997/009885 fails to teach the use of GM-CSF for stimulating the proliferation of neural

cells. Accordingly, the reference fails to anticipate the invention of claims 1 and 8 as amended herein, and applicants respectfully request the withdrawal of the rejection of claims 1 and 8 based on that reference.

Claims 1, 8, 14, 16 and 17 stand rejected under 35 USC 102(e) as being anticipated by US patent 6,897,060 (Bjornson). Applicants respectfully traverse this rejection.

Applicants have discovered the surprising result that a composition that includes GM-CSF as the sole active agent can be administered to endogenous cells *in vivo* to induce the proliferation of neural stem cells and neural progenitor cells. See Example 7 and the accompanying figures for data demonstrating the efficacy of the treatment. Claim 1 has been amended to specify the method consists of the step of administering a composition that consists essentially of GM-CSF. The '060 patent fails to teach or suggest a therapeutic methodology wherein GM-CSF is administered as the sole active component. As noted by the Examiner, Bjornson suggests that GM-CSF can be an additional compound included in a therapeutic composition and therapeutic treatment. However, Bjornson teaches the use of GM-CSF only in conjunction with the administration of additional bioactive material (e.g., cells). Bjornson is devoid of any teaching or suggestion that the proliferation of endogenous cells could be significantly increased by the mere administration of GM-CSF in the absence of any other treatments.

Bjornson also fails to teach that GM-CSF can be used to induce the proliferation of neural cells *in vitro*. Bjornson only discloses the use of GM-CSF in compositions that are transplanted into a patient. Therefore, Bjornson fails to provide any motivation for the sale of a kit that includes GM-CSF in combination with a cell culture medium.

Accordingly, applicants respectfully submit that Bjornson fails to teach the presently claimed invention and applicants respectfully request the withdrawal of the rejection of claims 1, 8 and 16 as being anticipated by Bjornson.

Claims 1, 2, 5, 8, 14, 16 and 17 stand rejected under 35 USC 102(e) as being anticipated by US 20050244965 (Weiss). Applicants respectfully traverse this rejection.

Applicants note that the 35 USC 102(e) date of the Weiss reference is July 30, 2002. The present invention claims priority to Japanese application no 2002-89624, filed on March 27, 2002. Therefore, applicants respectfully submit that the Weiss reference is not a proper 35 USC 102 art reference with regards to the present invention.

Applicants note that a certified copy of the foreign priority document has been previously provided to the US patent and Trademark Office. In further support of applicants' claim to the early foreign priority date of Japanese application no 2002-89624, applicants

submit herewith, attached as Exhibit A, a certified copy of an English language translation of the Japanese priority document, in accordance with 37 CFR 1.55 (4)(ii). Support for the currently claimed invention is found in the English language translation of the priority document at page 7, lines 6-12, the second full paragraph of page 7, all of page 8 and in Example 3. Applicants respectfully submit the claimed invention is entitled to the early claimed priority date of March 27, 2002 and that the Weiss reference does not constitute a prior art reference against the present invention. Accordingly, applicants request the withdrawal of the rejection of claims 1, 2, 5, 8, 14, 16 and 17 as being anticipated by US 20050244965 (Weiss).

The foregoing amendments and remarks are believed to be fully responsive to the various rejections raised by the Examiner in the Office Action mailed April 4, 2007. Applicants believe that this application is in condition for allowance, and respectfully request passage of the application to issuance.

The undersigned would welcome a telephonic interview with the Examiner if the Examiner believes that such an interview would facilitate resolution of any outstanding issues.

Respectfully submitted,
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